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Translation

PCT/EP2003/004032

PATENT COOPERATION TREATY

PCT

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
29798P WO		
International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/EP2003/004032	17 April 2003 (17.04.2003)	19 April 2002 (19.04.2002)
International Patent Classification (IPC) or national classification and IPC A61K 9/48		
Applicant BIOGHURT BIOGARDE GmbH & Co. KG		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
27 August 2003 (27.08.2003)	30 July 2004 (30.07.2004)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP2003/004032

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-16, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages 1-21, filed with the letter of 24 June 2004 (24.06.2004)

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: I

Basis of the report

The new claims 1 and 6 are based on the original claims 1 and 6, the claims having been clarified by incorporation of the features in the original claims 9 and 12.

Claim 9 is based on the original claim 9.

Claims 2-5, 7, 8, 10 and 11 correspond to the original claims with the same numbering.

Claims 12 to 20 correspond to the original claims 13 to 21.

Claim 21 is based on the original claim 22 and was redrafted as a claim for the second medical use, in conformity with European practice.

Claims 1-21 therefore comply with the requirements of PCT Article 34(2)(b), because their subject matter does not go beyond the disclosure in the international application as filed.

V. **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims		YES
	Claims	1-21	NO
Inventive step (IS)	Claims		YES
	Claims	1-21	NO
Industrial applicability (IA)	Claims	1-21	YES
	Claims		NO

2. Citations and explanations

1. Citations

Reference is made to the following documents:

D1: WO-A-01/84961
D2: EP-A-0 072 469
D3: WO-A-92/11294
D4: WO-A-02/078464.

2. Novelty (PCT Article 33(2))

It is stated in the present application, page 11, lines 26 to 30 that "the matrix may naturally also contain, along with the main ingredients or mixtures thereof, additional bioactive substances such as amino acids, vitamins, lipids, polyphenols, carbohydrates, trace elements, mineral substances and suitable derivatives thereof".
Consequently, the objections concerning novelty in relation to documents D1 to D3, which contain, along with the carrier material and the acetone-insoluble phospholipid ingredients, comparable additional bioactive substances, are maintained.

In the assessment of novelty of the subject matter of a claim, statements concerning an intended special type of use (e.g., "as a bioactive ingredient", claim 1) should be disregarded.

Document D1 discloses (see example 1) a capsule for use in the treatment of dementia, containing: a/ 15.6 wt.% phosphatidylcholine (PC), b/ 14.5 wt.% phosphatidylserine (PS), c/ 15.1 wt.% omega-3 fatty acid and d/ 24.1 wt.% vitamin E. The other examples, 2 to 5, disclose different functional nutrients such as cakes or bars which also contain comparable phospholipid-containing stable matrices. Consequently, the subject matter of claims 1-21 is not novel (PCT Article 33(2)).

Document D2 discloses (see page 15, line 1 to page 18, line 4) a dosage form (more particularly tablets and capsules) for oral administration, containing: a/ ascorbic acid (67 %), b/ lecithin (up to 30 %), c/ Avicel (up to 39 %). Consequently, the subject matter of claims 1, 2, 4, 6-12, 14-18, 20 and 21 is not considered to be novel (PCT Article 33(2)).

Document D3 discloses (see example 2.1 on page 36) a tablet or a capsule containing: a/ 17 wt.% new heparin derivative PE, b/ 45.5 wt.% PC + PS, c/ 28.4 wt.% lactose and d/ 5.7 wt.% microcrystalline cellulose. Consequently, the subject matter of claims 6-12 and 14-20 is not novel (PCT Article 33(2)).

3. Inventive step (PCT Article 33(3))

Since the subject matter of claims 1-21 is not novel, it does not involve an inventive step (PCT Article 33(3)).

4. Industrial applicability (PCT Article 33(4))

The subject matter of claims 1-21 complies with the requirements of PCT Article 33(4) with regard to industrial applicability.